

CLEAN VERSION OF ALL PENDING CLAIMS

1. (As filed) A vascular prosthesis comprising:
an expansible structure which is implantable within a body lumen; and
means on or within the structure for releasing methylprednisolone into the
body lumen to inhibit smooth muscle cell proliferation.
2. (As filed) A prosthesis as in claim 1, wherein methylprednisolone
is released at a rate between 5 $\mu\text{g/day}$ to 200 $\mu\text{g/day}$.
3. (As filed) A prosthesis as in claim 1, wherein methylprednisolone
is released at a rate between 10 $\mu\text{g/day}$ to 60 $\mu\text{g/day}$.
4. (As filed) A prosthesis as in claim 1, wherein methylprednisolone
is released at an initial phase wherein a rate of methylprednisolone release is between 0
 $\mu\text{g/day}$ to 50 $\mu\text{g/day}$ and a subsequent phase wherein a rate of methylprednisolone release
is between 5 $\mu\text{g/day}$ to 200 $\mu\text{g/day}$.
5. (As filed) A prosthesis as in claim 1, wherein methylprednisolone
is released at an initial phase wherein a rate of methylprednisolone release is between 5
 $\mu\text{g/day}$ to 30 $\mu\text{g/day}$ and a subsequent phase wherein a rate of methylprednisolone release
is between 10 $\mu\text{g/day}$ to 100 $\mu\text{g/day}$.
6. (As filed) A prosthesis as in claim 1, wherein methylprednisolone
is released at an initial phase wherein a rate of methylprednisolone release is between 40
 $\mu\text{g/day}$ to 300 $\mu\text{g/day}$ and a subsequent phase wherein a rate of methylprednisolone
release is between 1 $\mu\text{g/day}$ to 100 $\mu\text{g/day}$.
7. (As filed) A prosthesis as in claim 1, wherein methylprednisolone
is released at an initial phase wherein a rate of methylprednisolone release is between 40
 $\mu\text{g/day}$ to 200 $\mu\text{g/day}$ and a subsequent phase wherein a rate of methylprednisolone
release is between 10 $\mu\text{g/day}$ to 40 $\mu\text{g/day}$.

8. (As filed) A prosthesis as in claim 1, wherein methylprednisolone is released at a constant rate between 5 $\mu\text{g/day}$ to 200 $\mu\text{g/day}$.

9. (As filed) A prosthesis as in claim 1, wherein a total amount of methylprednisolone release is in a range from 100 μg to 10 mg.

10. (As filed) A prosthesis as in claim 1, wherein a total amount of methylprednisolone release is in a range from 300 μg to 2 mg.

11. (As filed) A prosthesis as in claim 1, wherein a total amount of methylprednisolone release is in a range from 500 μg to 1.5 mg.

12. (As filed) A prosthesis as in claim 1, wherein a mammalian tissue concentration of methylprednisolone at an initial phase is within a range from 0 $\mu\text{g/mg}$ of tissue to 100 $\mu\text{g/mg}$ of tissue.

13. (As filed) A prosthesis as in claim 1, wherein a mammalian tissue concentration of methylprednisolone at an initial phase is within a range from 0 $\mu\text{g/mg}$ of tissue to 10 $\mu\text{g/mg}$ of tissue.

14. (As filed) A prosthesis as in claim 1, wherein a mammalian tissue concentration of methylprednisolone at a subsequent phase is within a range from 1 picogram/mg of tissue to 100 $\mu\text{g/mg}$ of tissue.

15. (As filed) A prosthesis as in claim 1, wherein a mammalian tissue concentration of methylprednisolone at a subsequent phase is within a range from 1 nanogram/mg of tissue to 10 $\mu\text{g/mg}$ of tissue.

16. (As filed) A prosthesis as in claim 1, wherein the expansible structure is a stent or graft.

17. (As filed) A prosthesis as in claim 1, wherein the means for releasing methylprednisolone comprises a matrix formed over at least a portion of the structure.

18. (As filed) A prosthesis as in claim 17, wherein the matrix is composed of a material which undergoes degradation.

19. (As filed) A prosthesis as in claim 17, wherein the matrix is composed of a nondegradable material.

20. (As filed) A prosthesis as in claim 19, wherein methylprednisolone is released by diffusion through the nondegradable matrix.

21. (As filed) A prosthesis as in claim 17, wherein the matrix comprises multiple layers, wherein at least one layer contains methylprednisolone and another layer contains methylprednisolone, at least one substance other than methylprednisolone, or no substance.

22. (As filed) A prosthesis as in claim 21, wherein the at least one substance other than methylprednisolone is an immunosuppressive substance selected from the group consisting of rapamycin, mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506, zafurin, and methotrexate.

23. (As filed) A prosthesis as in claim 21, wherein the at least one substance other than methylprednisolone is an agent selected from the group consisting of anti-platelet agent, anti-thrombotic agent, and IIb/IIIa agent.

24. (As filed) A prosthesis as in claim 1, wherein the means for releasing methylprednisolone comprises a rate limiting barrier formed over at least a portion of the structure.

25. (As filed) A prosthesis as in claim 24, wherein methylprednisolone is released by diffusion through the rate limiting barrier.
26. (As filed) A prosthesis as in claim 1, wherein the means for releasing methylprednisolone comprises a reservoir on or within the structure containing methylprednisolone and a cover over the reservoir.
27. (As filed) A prosthesis as in claim 1, wherein methylprednisolone is on or within the expansible structure.
28. (As filed) A prosthesis as in claim 1, wherein methylprednisolone is disposed within a matrix or rate limiting membrane.
29. (As filed) A vascular prosthesis comprising:
an expansible structure implantable within a body lumen; and
a rate limiting barrier on the structure for releasing methylprednisolone into the body lumen to inhibit smooth muscle cell proliferation;
wherein the barrier comprises multiple layers, each layer comprising parylast or paralene and having a thickness in a range from 50 nm to 10 microns.
30. (As filed) A prosthesis as in claim 29, wherein methylprednisolone is released at a rate between 5 $\mu\text{g/day}$ to 200 $\mu\text{g/day}$.
31. (As filed) A prosthesis as in claim 29, wherein methylprednisolone is released at a rate between 10 $\mu\text{g/day}$ to 60 $\mu\text{g/day}$.
32. (As filed) A prosthesis as in claim 29, wherein at least one layer contains methylprednisolone and another layer contains methylprednisolone, at least one substance other than methylprednisolone, or no substance.
33. (As filed) A vascular prosthesis comprising:
an expansible structure;

a source of methylprednisolone on or within the structure, wherein the methylprednisolone is released from the source when the expansible structure is implanted in a blood vessel; and

a source of at least one other substance in addition to methylprednisolone on or within the structure, wherein the at least one additional substance is released from the source when the expansible structure is implanted in a blood vessel.

34. (As filed) A prosthesis as in claim 33, wherein the at least one additional substance is an immunosuppressive substance selected from the group consisting of rapamycin, mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506, zafurin, and methotrexate.

35. (As filed) A prosthesis as in claim 33, wherein the at least one additional substance comprises at least one agent selected from the group consisting of anti-platelet agent, anti-thrombotic agent, and IIb/IIIa agent.

36. (As filed) A prosthesis as in claim 33, wherein each source comprises a matrix, rate limiting membrane, or reservoir.

37. (As filed) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:
implanting a vascular prosthesis in the blood vessel; and
releasing methylprednisolone into the blood vessel so as to inhibit smooth muscle cell proliferation.

38. (Once Amended) A method as in claim 60, wherein methylprednisolone is released at a rate between 5 $\mu\text{g/day}$ to 200 $\mu\text{g/day}$.

39. (Once Amended) A method as in claim 60, wherein methylprednisolone is released at a rate between 10 $\mu\text{g/day}$ to 60 $\mu\text{g/day}$.

40. (Once Amended) A method as in claim 60, wherein methylprednisolone is released within a time period of 1 day to 45 days in a vascular environment.

41. (Once Amended) A method as in claim 60, wherein methylprednisolone is released within a time period of 7 days to 21 days in a vascular environment.

42. (Once Amended) A method as in claim 60, further comprising releasing at least one other substance in addition to methylprednisolone simultaneously with methylprednisolone release.

43. (Once Amended) A method as in claim 60, further comprising releasing at least one other substance in addition to methylprednisolone sequentially with methylprednisolone release.

44. (As filed) A method as in claim 42 or 43, wherein the at least one additional substance is an immunosuppressive substance selected from the group consisting of rapamycin, mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506, zafurin, and methotrexate.

45. (Once Amended) A method as in claim 60, wherein the releasing comprises delaying substantial release of methylprednisolone for at least one hour following implantation of the prosthesis.

46. (Once Amended) A method as in claim 45, wherein delaying release comprises slowing releasing methylprednisolone from a reservoir with a material that at least partially degrades in a vascular environment over said one hour.

47. (Once Amended) A method as in claim 45, wherein delaying release comprises slowing releasing methylprednisolone with a matrix that at least partially degrades in a vascular environment over said one hour.

48. (Once Amended) A method as in claim 45, wherein delaying release comprises slowing releasing methylprednisolone with a nondegradable matrix that allows diffusion of methylprednisolone through the nondegradable matrix after said one hour.

49. (Once Amended) A method as in claim 45, wherein delaying release comprises slowing releasing methylprednisolone with a rate limiting barrier that allows diffusion of methylprednisolone through the barrier after said one hour.

50. (As filed) A method as in any one of claims 47-49, wherein the prosthesis is coated with the matrix or barrier by spraying, dipping, deposition, or painting.

51. (Once Amended) A method as in claim 60, wherein the prosthesis incorporates methylprednisolone by coating, spraying, dipping, deposition, chemical bonding, or painting methylprednisolone on the prosthesis.

52. (As filed) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:
implanting a vascular prosthesis in the blood vessel; and
releasing methylprednisolone and at least one other substance in addition to methylprednisolone from the prosthesis when implanted in the blood vessel.

53. (As filed) A method as in claim 52, wherein the at least one additional substance is an immunosuppressive substance selected from the group consisting of rapamycin, mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506, zafurin, and methotrexate.

54. (As filed) A method as in claim 53, wherein the immunosuppressive substance is mycophenolic acid.

55. (Once Amended) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:
implanting a vascular prosthesis in the blood vessel; and
releasing methylprednisolone and at least one other substance in addition to methylprednisolone from the prosthesis when implanted in the blood vessel, wherein the immunosuppressive substance is mizoribine.

56. (Once Amended) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:
implanting a vascular prosthesis in the blood vessel; and
releasing methylprednisolone and at least one other substance in addition to methylprednisolone from the prosthesis when implanted in the blood vessel, wherein methylprednisolone is released within a time period of 2 days to 3 months.

57. (As filed) A method as in claim 52, wherein the at least one additional substance comprises at least one agent selected from the group consisting of anti-platelet agent, anti-thrombotic agent, and IIb/IIIa agent.

58. (As filed) A method as in claim 52, wherein methylprednisolone and the at least one additional substance are released simultaneously.

59. (As filed) A method as in claim 52, wherein methylprednisolone and the at least one additional substance are released sequentially.

60. (Added) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:
implanting a vascular prosthesis in the blood vessel; and
releasing methylprednisolone from the prosthesis into the blood vessel so as to inhibit smooth muscle cell proliferation.

61. (Added) A method as in claim 55, wherein methylprednisolone is released within a time period of 2 days to 3 months and mizoribine is released within a time period of 1 day to 45 days.